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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ASSISTANT COMMISSIONER FOR PATENTS
BOX FWC

Washington, D.C. 20231

Attorney's Docket Number: 04012.0188

Prior Application:

Art Unit: 1813

Examiner: L.F. Smith

SIR: This is a request for filing a

[X] Continuation [] Continuation-in-part [] Divisional application under 37 C.F.R.
§ 1.62 of pending prior application Serial No. 08/442,288 filed May 16, 1995
for VACCINE COMPOSITION CONTAINING ADJUVANTS
(Title of Invention)

by the following named inventor(s).

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	: UW220, P.O. Box 1539, King of Prussia, PA	19406-0939	USA
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	: Pala	Pietro	
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	: UW220, P.O. Box 1539, King of Prussia, PA	19406-0939	USA

The above-identified prior application in which no payment of the issue fee, abandonment of, or termination of proceedings has occurred, is hereby expressly abandoned as of the filing date of this new application. Please use all the contents of the prior application file wrapper, including the drawings, as the basic papers for the new application.

1. ☐ Enter the amendment previously filed on _____ under 37 C.F.R. § 1.116 but unentered, in the prior application.
2. ☒ A Preliminary Amendment is enclosed.
3. ☒ The filing fee is calculated on the basis of the claims existing in the prior application as amended at 1 and 2 above.

For	: Number Filed	: Number Extra	: Rate	: Basic Fee \$770.00
Total	:	:	:	:
Claims	: 14 -20=	: 0	: x\$ 22.00=	: \$
Independent	:	:	:	:
Claims	: 2 -3=	: 0	: x\$ 80.00=	:
Multiple Dependent Claim(s) (if applicable)	:	:	: +\$260.00=	:
			Total =	: \$770.00
			Reduction by ½ for	:
			filing by small entity	: -
			TOTAL FILING FEE =	: \$770.00

4. ☒ A check in the amount of \$ 770.00 to cover the filing fee is enclosed.
5. ☒ The Commissioner is hereby authorized to charge any fees including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, or credit any overpayment to Deposit Account No. 06-0916.
6. ☐ A new declaration is included since this application is a continuation-in-part which discloses and claims additional matter.

7. [XX] Amend the specification by inserting before the first line, the sentence:

--This application is a continuation of application Serial No. 08/442,288, filed May 16, 1995, now abandoned, which is a continuation of application Serial No. 08/356,372, filed February 17, 1995, which is the national phase entry of PCT/EP93/01524 filed June 15, 1993 claiming priority of UK9213559.9 filed June 25, 1992, UK9226283.1 filed December 17, 1992 and UK9304056.6 filed March 1, 1993.--

8. [] A verified statement claiming small entity status

[] is enclosed or [] is on file in the prior application.

9. [XX] Priority of application Serial No. 9213559.9 filed on June 25, 1992 in United Kingdom, application Serial No. 9226283 filed June 15, 1993 filed on December 17, 1992 in the United Kingdom, and application Serial No. 9304056.6 filed March 1, 1993 in the United Kingdom are claimed under 35 U.S.C. § 119. Certified copies

[] is enclosed or [X] are on file in the prior application.

10. [XX] The prior application is assigned of record to: SmithKline Beecham Biologicals (s.a.)

11. [XX] The power of attorney in the prior application is to at least one of the following: FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Reg. No. 22,540; Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg. No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Reilly, Reg. No. 27,932; Allen M. Sokal, Reg. No. 26,695; Robert D. Bajefsky, Reg. No. 25,387; Richard L. Stroup, Reg. No. 28,478; David W. Hill, Reg. No. 28,220; Thomas L. Irving, Reg. No. 28,619; Charles E. Lipsey, Reg. No. 28,165; Thomas W. Winland, Reg. No. 27,605; Basil J. Lewris, Reg. No. 28,818; Martin I. Fuchs, Reg. No. 28,508; E. Robert Yoches, Reg. No. 30,120; Barry W. Graham, Reg. No. 29,924; Susan Haberman Griffen, Reg. No. 30,907; Richard B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Robert E. Converse, Jr., Reg. No. 27,432; Clair X. Mullen, Jr., Reg. No. 20,348; Christopher P. Foley, Reg.

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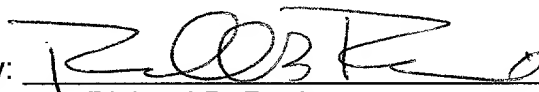
12. [XX] Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT and DUNNER, L.L.P., 1300 I Street, N.W., Washington, D.C. 20005-3315.
13. [] Recognize as associate attorney _____

 (name, address & Reg. No.)
14. [] Also enclosed is _____

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this application, including any extension in the parent application, serial no. 08/442,288, filed May 16, 1995, for the purpose of maintaining copendency between the parent application and this application, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to our Deposit Account No. 06-0916. A duplicate copy of this paper is enclosed for use in charging the deposit account.

It is understood that secrecy under 35 U.S.C. § 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 C.F.R. § 1.62 application, be it either this application or a prior application in the same file wrapper, the U.S. Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 
 Richard B. Racine
 Reg. No. 30,415

Date: August 12, 1997

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Rule 62 Continuation Applications of:)
PRIEELS, J.P. et al.)
)
Serial No. 08/442,288) Group Art Unit: 1813
Filed: May 16, 1995) Examiner: L.F. Smith
For: VACCINE COMPOSITION)
CONTAINING ADJUVANTS) VIA HAND DELIVERY

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Prior to the examination of this Rule 62 continuation application of parent application
Serial No. 08/442,288 filed May 16, 1995, please enter the following amendment.

IN THE CLAIMS:

Please cancel claims 1-5, 7, and 10-18.

Please add claims 19-32.

--19. A vaccine composition comprising:

(a) an antigen derived from the group consisting of Human Immunodeficiency
Virus (HIV) and Feline Immunodeficiency Virus (FIV);

(b) QS21; and

(c) 3-De-O-acylated monophosphoryl lipid A (3D-MPL).

20. A vaccine as claimed in claim 19 wherein the ratio of QS21:3D-MPL is from 1:10
to 10:1.

21. A vaccine composition as claimed in claim 19 capable of invoking a cytolytic T
cell response in a mammal to the HIV or FIV antigen.

22. A vaccine composition as claimed in claim 19 capable of stimulating interferon γ
production.

23. A vaccine composition as claimed in claim 20 wherein the ratio of QS21:3D-MPL is from 1:1 to 1:2.5.

24. A process for making a vaccine composition according to claim 19 comprising admixing QS21 and 3D-MPL with the HIV or FIV antigen.

25. A method for stimulating a cytotoxic T cell response in an animal comprising introducing into said animal a cytotoxic T cell response stimulating amount of the composition of claim 19.

26. A method for stimulating a γ -interferon response in an animal comprising introducing into said animal a γ -interferon response stimulating amount of the composition of claim 19.

27. A vaccine composition as claimed in claim 19 wherein the QS21 and the 3D-MPL synergistically enhance the immune response in an animal to the HIV or FIV antigen.

28. A method of enhancing the immune response in an animal to an Human Immunodeficiency Virus (HIV) or Feline Immunodeficiency Virus (FIV) antigen which comprises administering to the animal: (a) the HIV or FIV antigen, (b) QS21, and (c) 3D-MPL.

29. The method of claim 28 in which the animal is a human.

30. The method of claim 28 wherein the QS21 and the 3D-MPL are administered at a ratio of QS21:3D-MPL of from 1:10 to 10:1.

31. The method of claim 28 wherein the ratio of QS21:3D-MPL is from 1:1 to 1:2.5.

32. The method of claim 28 wherein the QS21 and 3D-MPL synergistically enhance the immune response.--

Rule 62 Cont. Appl. of
SN 08/442,288
Prieels, J.P. et al.

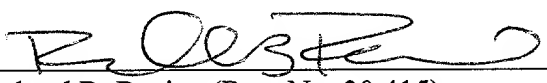
REMARKS

In this Rule 62 continuation application of Serial No. 08/442,288 filed May 16, 1995, applicants are canceling pending claims 1-5, 7, and 10-18 and presenting new claims 19-32. Applicants are canceling pending claims 1-5, 7, and 10-18 because the Examiner has informed the undersigned in a telephone conference on July 7, 1997 that such claims would be allowable in related application Serial No. 08/356,372 filed February 17, 1995. By the allowance of those claims in the '372 application, by a Notice of Allowance dated July 23, 1997, there is no need to move forward with the appeal in either the '372 application or the present application, for which appeal briefs had been filed on May 19, 1997.

Added claims 19-32 are directed to the use of QS-21 and 3D-MPL when the antigen is specifically defined as Human Immunodeficiency Virus (HIV) or Feline Immunodeficiency Virus (FIV) antigen.

If there is any fee due for this amendment, including a fee for an extension of time, please charge any such fee to Deposit Account No. 06-916.

Date: August 12, 1997


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